

REMARKS

Claims 37-41 and 44-106 are in the application. Claims 37-40, 61, 73, 77-79 and 98 have been amended to better clarify the invention. No new matter is believed added.

The Examiner has presented a restriction requirement under 35 USC 121 to the following two groups:

Group I, claims 37-41 and 44-70 drawn to multi-component dosage forms;
Group II, claims 71-106 drawn to a capsule dosage form.

Applicants respectfully disagree with the Examiner's interpretation of what claims 71-106 cover.

Claim 71 is dependent upon Claim 37. The preamble of claim 71 recites "The multi-component pharmaceutical dosage form according to Claim 37 wherein the solid matrix is composed of a pharmaceutical composition comprising". Claim 73 is an independent claim covering a multi-component dosage form similar to that of Claim 37. The difference between claim 37 and claim 73 is that claim 37 defines the solid matrix to be comprised of the copolymer formulation whereas claim 73 requires the multicomponent form to have the capsule shell comprised of the copolymer formulation. The subject matter of the formulation is the same, the resulting article of manufacture differs, e.g. linker subunit (matrix) and capsule component. The burden on the office does not differ with respect to the searching required for either component.

The Examiner has not shown that there is a serious search burden, nor that these two claims are or have achieved a separate status in the art. They should not be separately classified as they require the same two components to be present, a solid sub-unit and a capsule component. It is what each component is made of that would determine the difference between the two independent claims.

As the restriction is flawed as to what is contained within the two groups, Applicants can not elect until the restriction is properly made.

However, Applicants can assist the Examiner in the election of species as presented on Page 4 of the Office Action.

With respect to:

- 1) The two HPC polymers of differing molecular weight, Applicants elect that of claim 38.
- 2) Lubricant: stearyl alcohol
- 3) Dissolution modifying excipient: disintegrant.
- 4) Specific Disintegrant (as found in claim 46, not in claim 81 as noted by the Examiner) is sodium starch glycollate.
- 5) Surfactant: sodium dodecyl sulphate.
- 6) Absorption enhancer: Vitamin E-TPGS

However, Applicants note that the claimed formulations include more than one surfactant and the specific examples herein have a combination of polyoxypropylene-polyoxyethylene block copolymers and sodium dodecyl sulphate.

- 7) Second Dissolution modifying excipient should include a swellable solid in the listing above for species election, however Applicants will elect croscarmellose sodium.

To assist the Examiner, perhaps an election of a formulation such as that shown in Example 107 or 108 might be simpler?

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. If any additional fees or charges are required by this paper the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,

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